

**K153165 NEPHROCHECK Test Kit, ASTUTE140 Meter,
NEPHROCHECK Liquid Controls Kit, NEPHROCHECK
Calibration Verification (Cal Vers) Kit**Jun 1, 2016
212 days to decisionK153165 · Product code: **PIG** · Chemistry
Source: <https://www.510kdatabase.net/k153165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Acute Kidney Injury Test System (PIG)
Date received	Nov 2, 2015
Decision date	Jun 1, 2016
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Astute Medical, Inc.
Location	San Diego, CA, US
Contact	Karin Hughes
510(k) history	3 submissions · 2 cleared · 2014-2017

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